

40 CFR Part 180

[PP 4F4402/R2149; FRL-4963-6]

RIN 2070-AB78

Inclusion Bodies of Multi-Nuclear Polyhedrosis Virus of *Anagrapha falcifera*; Exemption From the Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a pesticide tolerance for residues of the microbial pest control agent inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera* (celery looper) in or on all raw agricultural commodities. Biosys requested this tolerance exemption that eliminates the need to establish a maximum permissible level for residues of *Anagrapha falcifera* multi-nuclear polyhedrosis virus.

EFFECTIVE DATE: This regulation becomes effective July 19, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4402/R2149], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in

electronic form must be identified by the docket number [PP 4F4402/R2149]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: CS #1, 5th Floor, 2800 Crystal Drive, Crystal City, VA 22202, (703) 308-8733; e-mail: hollis.linda@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of November 2, 1994 (59 FR 54902), which announced that Biosys, Palo Alto, CA 94303, had submitted a pesticide petition, PP 4F4402, to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), exempt from the requirement of a tolerance the residues of the microbial pest control agent inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera* in or on all raw agricultural commodities when used to control certain lepidopteran pest species.

No comments were received in response to the notice of filing.

Residue Chemistry Data

Residue chemistry data are necessary only if the submitted toxicology studies indicate that additional Tier II or III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; therefore, Tier II or III data were not required.

Toxicology Data

Toxicology data considered in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature with the exception of an acute oral toxicity study. Waivers include an acute dermal toxicity study in the guinea pig, an acute inhalation toxicity study in the rat, a primary eye irritation study in the rabbit, and a cell culture study. Findings from the open scientific literature showed no toxic, pathogenic, or adverse effects.

Reference Dose (RfD) and maximum permissible intake (MPI) considerations

are not relevant to this petition because of this low toxicity and lack of pathogenicity or infectivity as reported in the open scientific literature.

Based on the information cited above, the Agency concludes that the establishment of a tolerance for the active ingredient *Anagrapha falcifera* multi-nuclear polyhedrosis virus is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 4F4402/R2149] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2,

1921 Jefferson Davis Highway,
Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 4F4402/R2149], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:

opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-

354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 3, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1149, to read as follows:

§ 180.1149 Inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera*; exemption from the requirement of a tolerance.

The microbial pest control agent inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera* is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used to control certain lepidopteran pest species.

[FR Doc. 95-17602 Filed 7-18-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 0F3885/R2152; FRL-4966-5]

RIN 2070-AB78

Burkholderia (Pseudomonas) Cepacia Type Wisconsin; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the biological pesticide *Burkholderia (Pseudomonas) cepacia* type Wisconsin in or on all raw agricultural commodities, resulting from use on plant roots or seedling roots. EPA is issuing this regulation on its own

initiative. The rule amends the existing tolerance exemption for this organism, which is limited to the seed treatment use.

EFFECTIVE DATE: This regulation becomes effective July 19, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 0F3885/R2152], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 0F3885/R2152]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, Biopesticide and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS51L6, Crystal Station #1, Arlington, VA 22202, (703)-308-8263; e-mail: greenway.denise@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 7, 1995 (60 FR 30048), EPA issued a proposed rule that